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| 10/807,869 | 03/23/2004 | Don L. Keim | 1760-298 | 5497 |
| 32905 | 7590 | 07/11/2006 | EXAMINER | |
| JONDLE & ASSOCIATES P.C. 858 HAPPY CANYON ROAD SUITE 230 CASTLE ROCK, CO 80108 | | | BAUM, STUART F | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1638 | |
| DATE MAILED: 07/11/2006 | | | | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|-------------------------------------|--|
| Office Action Summary | Application No. 10/807,869 | Applicant(s) KEIM, DON L. | |
| | Examiner Stuart F. Baum | Art Unit 1638 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 March 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-28 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>6/2/05, 4/20/06</u> <u>10/22/04</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Claims 1-28 are pending and are examined in the present office action.

Claim Objection

2. Claims 1, 6, 23 and 24 are objected to for the inclusion of a blank. It is assumed that the blanks will be replaced by the deposit accession numbers.

Claim 1 is objected to for the omission of "A" before "seed of cotton line..." because only a single invention can be claimed. Amending the claim to read --A seed of cotton line...-- will obviate this objection.

Claim 4 is objected to for the omission of "A" before "protoplasts produced from..." and the use of "protoplasts" because only a single invention can be claimed. Amending the claim to read --A protoplast-- before "produced from..." will obviate this objection.

Claim 21 is objected to for the inclusion of the phrase "...the cotton plant of claim 2 with a transgene encoding a protein selected from the group consisting of stearyl ACP desaturase, ...". The specification only teaches transformation of a plant with an antisense gene of stearyl-ACP desaturase (see page 24, paragraph 00116). In addition, the term "stearyl-ACP desaturase" in the specification claims an old term for the enzyme of EC 1.14.99.6, which has been changed to "stearyl-ACP desaturase" for EC 1.14.19.2. Either term would be proper in the claims, but the claims and the specification should be consistent in the spelling. These objections can be obviated by amending the claim by deleting "stearyl-ACP desaturase", after "of" and before "fructosyltransferase" and inserting --or encoding an antisense of stearyl-ACP desaturase-- after the word "enzyme" and before the period (.) at the end of the claim.

Deposit Rejection

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The invention appears to employ novel plants. Since the plant is essential to the claimed invention it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If the plant is not so obtainable or available, the requirements of 35 USC 112 may be satisfied by a deposit of the plant. A deposit of 2500 seeds of each of the claimed embodiments is considered sufficient to ensure public availability. The specification does not disclose a repeatable process to obtain the plant and it is not apparent if the plant is readily available to the public. It is noted that on page 35 of the specification that applicants intend to deposit the plant but there is no indication in the specification as to duration of the deposit, or viability testing or replacement. If the deposit is made under the terms of the Budapest Treaty, then an affidavit or declaration by applicants, or a statement by an attorney of record over his or her signature and registration number, stating that the specific strain has been deposited under the Budapest Treaty and that the strain will be irrevocably and without

Art Unit: 1638

restriction or condition released to the public upon the issuance of a patent, would satisfy the deposit requirement made herein.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 C.F.R. 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that

- (a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;
- (b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;
- (c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;
- (d) a test of the viability of the biological material at the time of deposit (see 37 CFR 1.807); and,
- (e) the deposit will be replaced if it should ever become inviable.

It is noted that Applicants intend to deposit seed of this invention (see page 32 of the specification), but the conditions under which the deposit will be made is unclear. There is no indication in the specification as to the duration that the deposit will be maintained, the viability of the biological material at the time of deposit, or the replacement of inviable seeds.

Applicant is required to make the necessary corrections.

Written Description

4. Claims 8-10 and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claims 8-9 are drawn to a hybrid cotton seed and plant produced by the method of producing an F1 hybrid cotton seed, wherein the method comprises crossing the plant of claim 2 with a different cotton plant and harvesting the resultant seed. Claims 24-28 are drawn to a method of introducing a desired trait into cotton cultivar 02X25R comprising crossing said plant with another cotton cultivar that comprises a desired trait to produce progeny plants, selecting one or more progeny plants that have the desired trait and crossing said plant with 02X25R to produce backcross progeny plants, selecting for backcross progeny plants having the desired trait and the physiological and morphological characteristics of cotton cultivar 02X25R listed in Table 1 to produce selected backcross plants and repeating the above steps to produce selected second or higher backcross progeny plants comprising the desired trait and all the physiological and morphological characteristics of cotton cultivar 02X25R listed in Table 1; wherein the desired trait is selected from claims 26-28.

The specification does not describe the other cotton plant or plants that are to be crossed with 02X25R nor is there a description of their genetic, morphological, and/or physiological background. It is known in the art that any plant derived from the crossing of two different plants will be an F1 hybrid plant that is heterozygous at all loci, therefore, the hybrid plant will

Art Unit: 1638

contain 50% of the alleles from the 02X25R cotton plant and 50% of the alleles from the other cotton plant. The 02X25R cotton plant, as well as its seeds and parts thereof, is the claimed invention, so a plant that contains only 50% of the alleles of the 02X25R cotton plant is not the same as the claimed 02X25R cotton plant, which would have 100% of its alleles. Furthermore, claims 9 and 10 read on an additional generation of out-crossing to a non-02X25R cotton parent so that seed with as little as 25% of the 02X25R alleles would be produced. Moreover, the genetic, morphological, and/or physiological characteristics of the claimed hybrids are not described in the specification. Since the claimed invention is derived from crossing 02X25R with any cotton plant, there could conceivably be hundreds of hybrids, each with different genetic, morphological, and/or physiological characteristics due to each having different “other” parents and the specification does not describe these hundreds of hybrids.

The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern US Patent 5,850,009, column 4, lines 41-46); therefore, Applicant has not described the myriad of different hybrids that may be produced from the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder.

The Federal Circuit has recently clarified the application of the written description requirement. The court stated that a written description of an invention “requires a precise definition, such as by structure, formula, [or] chemical name, of the claimed subject matter sufficient to distinguish it from other materials.” *University of California v. Eli Lilly and Co.*,

Art Unit: 1638

119 F.3d 1559, 1568; 43 USPQ2d 1398, 1406 (Fed. Cir. 1997). The court also concluded that “naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.” *Id.* Further, the court held that to adequately describe a claimed genus, Patent Owner must describe a representative number of the species of the claimed genus, and that one of skill in the art should be able to “visualize or recognize the identity of the members of the genus.” *Id.*

See MPEP Section 2163, page 156 of Chapter 2100 of the August 2001 version, column 2, bottom paragraph, where it is taught that

[T]he claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function. A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence.

Given the claim breadth and lack of guidance as discussed above, the specification fails to provide an adequate written description of the genus of sequences as broadly claimed. Given the lack of written description of the claimed genus of sequences, any method of using them, such as transforming plant cells and plants therewith, and the resultant products including the claimed transformed plant cells and plants containing the genus of sequences, would also be inadequately described. Furthermore, the specification fails to provide an adequate written description of the broadly claimed breeding partners comprising a multitude of non-exemplified genes, or the resultant progeny. Therefore, any methods of using the inadequately described progeny would themselves be inadequately described. Accordingly, one skilled in the art would not have recognized Applicant to have been in possession of the claimed invention at the time of

Art Unit: 1638

filing. See the Written Description Requirement guidelines published in Federal Register/ Vol. 66, No. 4/ Friday January 5, 2001/ Notices: pp. 1099-1111.

Enablement

5. Claims 8-10 and 24-28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claims 8 and 9 are drawn to a hybrid cotton seed and plant produced by the method of producing an F1 hybrid cotton seed, wherein the method comprises crossing the plant of claim 2 with a different cotton plant and harvesting the resultant seed. Claims 24-28 are drawn to a method of introducing a desired trait into cotton cultivar 02X25R comprising crossing said plant with another cotton cultivar that comprises a desired trait to produce progeny plants, selecting one or more progeny plants that have the desired trait and crossing said plant with 02X25R to produce backcross progeny plants, selecting for backcross progeny plants having the desired trait and the physiological and morphological characteristics of cotton cultivar 02X25R listed in Table 1 to produce selected backcross plants and repeating the above steps one or more times in succession to produce selected second or higher backcross progeny plants comprising the desired trait and all the physiological and morphological characteristics of cotton cultivar 02X25R listed in Table 1 and as determined at the 5% significance level; wherein the desired trait is selected from claims 26-28.

The specification only characterizes the exemplified cotton cultivar in terms of its collection of morphological traits. No guidance has been provided for any genetic locus conferring any of the multitude of traits. Furthermore, no guidance has been provided for the genetic, morphological or physiological makeup of any of a multitude of non-exemplified breeding partners, or for any of a multitude of progeny containing at most only a portion of the uncharacterized exemplified cultivar's genome as well as some or all of the uncharacterized non-exemplified breeding partner's genome. In addition, no guidance has been provided for the expression of any individual or combination of traits in said progeny. It is noted that the F1 hybrid plants of claim 9 would contain at least 50% of the uncharacterized genome of the multitude of non-exemplified breeding partners.

Thus, the specification provides no guidance for how to use a multitude of progeny plants with at least 50% of its genome being from an uncharacterized breeding partner, and at most the remaining 50% being from the exemplified but genetically uncharacterized cultivar.

The specification does give any guidance as to the other cotton plant or plants that are to be crossed with 02X25R nor is there any guidance as to their genetic, morphological, and/or physiological background. It is known in the art that any plant derived from the crossing of two different plants will be an F1 hybrid plant that is heterozygous at all loci; therefore, the hybrid plant will contain 50% of the alleles from the 02X25R cotton plant and 50% of the alleles from the other cotton plant. The 02X25R cotton plant, as well as its seeds and pads thereof, is the claimed invention, so a plant that contains only 50% of the alleles of the 02X25R cotton plant is not the same as the claimed 02X25R cotton plant, which would have 100% of its alleles. Furthermore, claims 9 and 10 read on an additional generation of out-crossing to a non-02X25R

Art Unit: 1638

cotton parent so that seed with as little as 25% of the 02X25R alleles would be produced.

Moreover, the genetic, morphological, and/or physiological characteristics of the claimed hybrids are not described in the specification. Since the claimed invention is derived from crossing 02X25R with any cotton plant, there could conceivably be hundreds of hybrids, each with different genetic, morphological, and/or physiological characteristics due to each having different "other" parents and the specification does not describe these hundreds of hybrids in terms of their traits, or provide any guidance regarding their use and therefore, it would not enable one skilled in the art to make and/or use the claimed invention.

The art teaches that the genetic variation among individual progeny of a breeding cross allows for the identification of rare and valuable new genotypes but that these new genotypes are neither predictable nor incremental in value, but rather the result of manifested genetic variation combined with selection methods, environments and the actions of the breeder (Kevern, US Patent 5,850,009, column 4, lines 41-46). The nature of the art at the time of Applicant's invention was such that one of skill in the art could not reasonably predict what the product of a cross between two inbred parental plants would be without a reduction to practice. The art teaches that "Even if an inbred in hybrid combination has excellent yield (a desired characteristic), it may not be useful because it fails to have acceptable parental traits such as seed yield, seed size, pollen production, plant height, etc". (Carlone, U.S. Patent 5,763,755, column 2, lines 11-14). The art teaches that based on the number of segregating genes, the frequency of occurrence of any individual with a specific genotype is less than 1 in 10,000 and that even if the entire genotype of the parents has been characterized and the desired phenotype is known, only a few, if any individuals having the desired genotype may be found in a large F₂ or S₀ population

Art Unit: 1638

and that typically the genotype of neither the parents nor the desired genotype is known in detail (see Segebad, U.S. Patent 5,304,719, in particular the paragraph spanning columns 2-3).

The art also teaches that the number of genes affecting the trait of primary economic importance can be in the range of 10-1000 genes and that inbred lines which are used as parents for breeding crosses differ in the number and combination of these genes (Segebad, U.S. Patent 5,367,109, column 2, lines 60-64). Segebad ('109) also teaches that one of the largest plant breeding programs in the world does not have a sufficiently large breeding population to be able to rely upon "playing the numbers" to obtain successful research results and that plant breeders use their skills, experience and intuitive ability to select inbreds having the necessary qualities (column 4, 1st and 2nd paragraphs). Hence, given the fact that one of skill in the art cannot reasonably predict the number of genes that affect the traits of the parental inbred lines of a inbred cotton plant, it is unclear how one of skill in the art could reasonably predict how to make and use the claimed cotton plants and methods of making a cotton plant using a second or filial non-exemplified cotton plant produced from Applicant's exemplified inbred cotton plant.

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been provided by one skilled in the art to identify, isolate and evaluate a multitude of non-exemplified transgenes; to evaluate and obtain a multitude of non-exemplified breeding partners; or to evaluate their ability to confer useful traits to the exemplified cultivar without eliminating the background collection of useful traits that the exemplified cultivar exhibits.

Claim Rejections - 35 USC §§ 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 8-10 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Gebhardt et al (November, 2004, U.S. Patent Number 6,815,584 B1).

Applicants have claimed plants and seeds produced from 02X25R cotton. However, it appears that the claimed plants and seeds are the same as the prior art cotton cultivar DP 2379, given that each has the same characteristics, including: intermediate plant habit, lodging erect, petal spot absent. Alternatively, if the claimed plants and seeds of 02X25R are not identical to DP 2379, then it appears that DP 2379 only differs from the claimed plants and seeds due to minor morphological variation, wherein said minor morphological variation would be expected to occur in different progeny of the same cultivar, and wherein said minor morphological variation would not confer a patentable distinction to 02X25R. Thus the claimed invention was

Art Unit: 1638

prima facie obvious as a whole to one of ordinary skill in the art at the time it was made, if not anticipated by DP 2379 cotton.

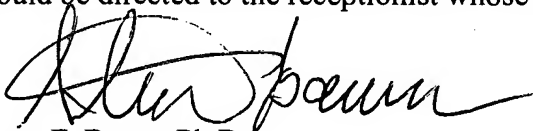
7. Claims 1-8 and 10-26 are deemed free of the prior art, given the failure of the prior art to teach or suggest an exemplified cotton plant which possesses a unique genetic complement and unique collection of traits as that of cotton line 02X25R, or methods of using said cotton line.

8. No claims are allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Stuart F. Baum whose telephone number is 571-272-0792. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anne Marie Grunberg can be reached at 571-272-0975. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.



Stuart F. Baum Ph.D.

Patent Examiner

Art Unit 1638

June 6, 2006

STUART F. BAUM, PH.D.
PATENT EXAMINER